

REMARKS

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-93 are pending, wherein no claims have been amended, added or cancelled. Reconsideration and allowance for the above-identified application are now respectfully requested in view of the following remarks.

The claimed invention involves dental bleaching compositions that at a minimum include 1) a dental bleaching agent, 2) potassium nitrate in a specified range, 3) a solvent, 4) a tackifying agent, and 5) a carrier that is substantially free of abrasives (sometimes defined as being less than 20% by weight of the composition). In order to establish that the claims are *prima facie* obvious, the Examiner bears the burden of establishing that the cited art teaches or suggests a dental bleaching composition that includes each and every one of elements 1) – 5) noted above. As will be shown below, the Office Action fails to show where the prior art teaches or suggests a dental bleaching composition that includes each and every one of elements 1) – 5). Accordingly, the Examiner fails to state a *prima facie* case of obviousness relative to any of the claims.

The Office Action rejects claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-93 under 35 U.S.C. § 103(a) as being unpatentable over McLaughlin (US 6,108,850) and Shimada et al. (US 5,626,837). Applicants submit that as one considers the totality of what is taught in McLaughlin, it becomes apparent that McLaughlin does not disclose or suggest the combination of elements recited in the claims, either alone or if combined with Shimada et al.

Claim 41 defines a dental bleaching composition that is substantially free of abrasives for bleaching and desensitizing a person's teeth. The bleaching composition comprises a dental bleaching agent in an amount in a range of 10% to about 30% by weight so as to have a tooth bleaching effect when contacted with a person's teeth, the dental bleaching agent comprising at least one peroxide. The composition also includes potassium nitrate in a range of about 0.01% to about 2% by weight so as to result in reduced tooth sensitivity that may be caused by the dental bleaching agent in the absence of potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth. Finally, the composition includes "a carrier that is substantially free of abrasives into which [the] dental bleaching agent and potassium nitrate are dispersed such that the dental bleaching composition contains less than 20% by weight of an abrasive, the carrier comprising a solvent and a tackifying agent". McLaughlin fails to disclose or suggest the combination of elements recited in claim 41, and Shimada et al. fails to cure the deficiencies of McLaughlin.

For example, claim 41 requires the combination of 1) a dental bleaching agent, 2) potassium nitrate, and a carrier comprising 3) a solvent and 4) tackifying agent and 5) that is substantially free of abrasives (*i.e.*, so that the dental bleaching composition contains less than 20% by weight of an abrasive). McLaughlin, when considered and properly interpreted, discloses an abrasive gel or paste whitening dentifrice suitable for scrubbing and whitening teeth that includes a peroxide, an abrasive, a thickener (*see* col. 3, lines 38-61), and optionally potassium nitrate (*see* col. 4, lines 9-12; col. 7, lines 6-15). McLaughlin cannot, in the absence of improper hindsight, be reasonably interpreted as disclosing a non-abrasive dental bleaching and desensitizing composition that includes 1) a dental bleaching agent, 2) potassium nitrate in the specified range(s), 3) a solvent, 4) a tackifying agent, and 5) less than 20% of an abrasive.

First, as pointed out in response to the previous Office Action and confirmed by the present Office Action, the main basis for alleging that claim 41 is obvious over McLaughlin is Example 4. Example 4 discloses a toothpaste composition that includes 10% hydrogen peroxide, 1% potassium nitrate, 83.5% of a “paste carrier” of unspecified constituents, and other minor components that are not germane to the rejection of claim 41 (*i.e.*, “flavoring agent 1%”, “aloe vera 2%”, “titanium dioxide 1%” and “sodium lauryl sulfate 1.5%”). Example 4 further teaches that “the formulation [of Example 4] comprising the bleaching compound is placed on the toothbrush with a catalyst embedded into one or more of the bristles of the brush, or with a catalytic agent embedded in a fabric bonded to the head of the brush”. Col. 7, lines 22-26. Given the fact that the toothpaste composition of Example 4 includes a “paste carrier” and is applied using a “toothbrush”, one of ordinary skill in the art would understand the toothpaste composition of Example as inherently including more than 20% by weight of an abrasive (*i.e.*, as a major component of the “paste carrier”, which makes up 83.5% of the toothpaste of Example 4).

It is well known to those of ordinary skill in the art that the term “toothpaste” refers to dentifrices that typically include a substantial quantity of an abrasive. For example, the publicly available web document attached hereto as Exhibit A hereto teaches the following: “A modern *toothpaste* has many things to do. It *must have abrasives* to scour off bacterial films.... Hydrated silica is the transparent *abrasive* used in gel toothpastes, and in the clear parts of striped toothpaste.” Exhibit A, Ingredients – Toothpaste, <http://sci-toys.com/ingredients/toothpaste.html> (01/26/2010), p. 1 (emphasis added).

As further evidence that the toothpaste composition in Example 4 of McLaughlin includes an abrasive, Applicants refer to the publicly available web document attached as Exhibit B hereto, which teaches the following: “*Toothpaste abrasives* scrub away plaque, help remove food stains from teeth, and polish tooth surfaces.” Exhibit B, Dental Health, Toothpaste—is There A Difference?, HealthNews More Natural Health, <http://www.healthnews.com/dental-health/toothpaste-there-difference-200.html> (01/26/2010), p. 2 (emphasis added).

Applicants further refer to the publicly available web document attached as Exhibit C hereto, which teaches the following: “**Abrasives:** Abrasives give toothpaste its cleaning power. They remove stains and plaque, as well as polish teeth. Common abrasives include calcium phosphates, alumina, calcium carbonate, and silica. *Toothpaste should be abrasive enough to remove plaque and stains, but not abrasive enough to damage tooth enamel.*” Exhibit C, Everything You Wanted to Know About Toothpaste, Toothpaste – What’s In It?, <http://www.saveyoursmile.com/toothpaste/toothpaste-c.html> (01/26/2010), p. 1 (italics added).

Consistent with the foregoing articles, which establish that toothpaste compositions, such as the one disclosed in Example 4 of McLaughlin, typically include an abrasive, McLaughlin itself discloses the use of abrasive materials when making toothpaste compositions suitable for scrubbing teeth. Col. 3, lines 37-49. The teaching in McLaughlin regarding the desirability of including an abrasive is further evidence that one of ordinary skill in the art would understand the toothpaste embodiment of Example 4 to include an abrasive material. Moreover, one of ordinary skill in the art would understand the “paste carrier” of Example 4 to include an abrasive material in sufficient quantity as to impart an abrasive action sufficient to clean teeth during brushing (*i.e.*, more than 20%).

In any event, while Example 4 does not explicitly use the term “abrasive” but rather a “paste”, it likewise does not use the terms “solvent” and “tackifying agent” as required by claim 41. As a result, simply referring to Example 4 is insufficient to establish that claim 41 is *prima facie* obvious. The Examiner must look elsewhere in McLaughlin to find mention of the solvent and tackifying agent required in claim 41. However, in the context in which the “thickening agent” (*i.e.*, the alleged “tackifying agent”) and water are disclosed in McLaughlin outside of Example 4, it becomes readily apparent that a thickening agent and solvent are only disclosed in the context of a composition that also includes an abrasive (*see* col. 3, lines 50-61):

When an abrasive material is included the vehicle may contain *water*, humectant, surfactant, and a *thickener*. Examples of humectants are glycerin, sorbitol, and polyethylene glycol (molecular weight 200-1000). Both mixtures of humectants and single humectants can be employed in the composition of the invention. *Thickeners may be incorporated in the abrasive component* such as natural and synthetic gums such as carrageenan, xanthan gum, sodium carboxymethyl cellulose, starch, polyvinylpyrrolidone, hydroxyethylpropylcellulose, hydroxybutyl methyl cellulose, hydroxypropyl methyl cellulose, and hydroxyethyl cellulose.

Col. 3, lines 50-61 (emphasis added). In all cases where a thickening agent and solvent are mentioned in McLaughlin, they are included together with the “abrasive material” (or “abrasive component”). *Id.* Nowhere does McLaughlin disclose or suggest a “paste” composition that includes both a solvent and thickening agent but not a substantial quantity of an abrasive material. It is therefore improper for the Examiner to assert that Example 4 inherently includes a “carrier comprising a solvent and a tackifying agent” but not an abrasive. This is selective interpretation and hindsight reconstruction of the prior art using the elements recited in claim 41 as a template rather than a fair and objective reading of McLaughlin in the absence of impermissible hindsight bias.

Moreover, statements made during prosecution of McLaughlin by the examiner and McLaughlin confirm that the “paste” compositions of McLaughlin include an abrasive. In the first office action dated April 8, 1999 (“Office Action”), a copy of which is attached hereto as Exhibit D, the Examiner rejected claims 1-6, 9, 11, 16-21 and 23 under 35 U.S.C. § 102(b) as being anticipated by Cornell (U.S. Patent No. 5,032,178). Exhibit D, Office Action, p. 4. In making this rejection, the examiner stated that “[s]ince a *paste* is disclosed, an *abrasive* would be inherent in the formulation.” *Id.* (emphasis added). This is further evidence that one of ordinary skill in the art would consider the term “paste” to imply the inclusion of an abrasive.

In response to the Office Action, the patentee filed an amendment dated July 12, 1999 (“Amendment”). In response to the rejection of the claims over Cornell, McLaughlin did not dispute that the term “paste” ordinarily implies the inclusion of an abrasive. Instead, McLaughlin merely stated that “Cornell adds a silica ‘gelling’ agent and not an abrasive. In fact, Applicant [McLaughlin] respectfully points out that the compositions of Cornell are not practical for use as an abrasive gel or scrubbing compound.” Exhibit E, Amendment, p. 8. Because McLaughlin does, in fact, disclose an abrasive, which renders the McLaughlin composition “practical for use as an abrasive gel or scrubbing compound” (*see id.*), one of ordinary skill in

the art would understand the “paste carrier” within the toothpaste composition of Example 4 of McLaughlin to inherently include an abrasive. This interpretation is consistent with the statement made by the examiner of the McLaughlin patent that “[s]ince a paste is disclosed, an abrasive would be inherent in the formulation.” Exhibit D, Office Action, p. 4.

Accordingly, there is no teaching, suggestion, motivation or other reason that would have prompted one of ordinary skill in the art to modify McLaughlin in order to obtain the presently claimed dental bleaching composition that includes 1) a dental bleaching agent, 2) potassium nitrate, 3) a solvent and 4) thickening agent and 5) which is substantially free of abrasives (*e.g.*, less than 20% by weight of an abrasive). As Shimada et al. was only cited as allegedly disclosing the use of antimicrobial agents, pH adjusters, actives, and humectants, Shimada et al. fails to cure the deficiencies of McLaughlin. Applicants therefore submit that claim 41 is unobvious over the combination of McLaughlin and Shimada et al.

All remaining claims similarly claim a dental bleaching composition, or a method of using a dental bleaching composition, that includes a dental bleaching agent, potassium nitrate, and carrier comprising a solvent and a tackifying agent and that is substantially free of abrasives. The remaining claims are therefore patentable over the combination of McLaughlin and Shimada et al. for at least those reasons given above relative to claim 41. In addition, claims 46, 65 and 81 claim an amount of potassium nitrate (about 0.5%) in combination with the other recited elements that is not taught or suggested by McLaughlin. Moreover, claims 59 and 77 claim a range of potassium nitrate (about 0.05-1%) in combination with the other recited elements that is neither taught nor suggested by McLaughlin.

The Office Action rejects claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-93 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,306,370 (the “370 patent”). In response, Applicants incorporate by reference arguments made in previous amendments explaining that the claims of the present invention define narrowly tailored concentration ranges of potassium nitrate that are neither taught nor suggested by either the claims or the specification of the ‘370 patent. Moreover, Applicants incorporate by reference and refer to the Declaration of Dan E. Fischer under 37 CFR § 1.132 setting forth and explaining that using relatively low quantities of potassium nitrate (*e.g.*, 0.5%) rather than larger quantities (*e.g.*, 3%) was surprisingly and unexpectedly found to reduce tooth and oral sensitivity caused by the dental bleaching agent more effectively than when a higher, conventionally-used quantity of potassium nitrate (*e.g.*, 3%)

was used. Because potassium nitrate was known to be a desensitizing agent, it would not be obvious that using less potassium nitrate would be more effective as a desensitizing agent than the accepted practice of using more potassium nitrate (*e.g.*, 3%). Therefore, the claims of the present application claim a specifically defined category of dental bleaching compositions that have unpredictably superior results compared to the full range of dental bleaching compositions within the scope of the claims of the '370 patent.

For example, claim 1 of the '370 patent claims potassium nitrate in an amount "of at least about 0.1%". According to the specification of the '370 patent, the amount of potassium nitrate can be as high as 50% by weight. Col. 6, lines 53-55 ("the inventive compositions may preferably include potassium nitrate in a wide range from about 0.1% to about 50% by weight of the whitening composition"). Accordingly, when the amount specified in claim 1 of the '370 patent is interpreted in light of the specification, it is readily apparent that the claimed range of claim 1 is essentially about 0.1-50%. This range is so broad as to hardly be suggestive of the narrowly tailored ranges set forth in the claims of the present application (*i.e.*, about 0.01-2% (claims 41, 72 and 86), about 0.05-1% (claims 59 and 77), and about 0.5% (claims 46, 61, 65 and 81)).

Moreover, the comparative study clearly showed that using an amount of potassium nitrate (*i.e.*, 0.5%) within the narrowly tailored ranges of the present application was far more effective in reducing sensitivity caused by the dental bleaching agent than using an amount outside the ranges (*i.e.*, 3%). If using 3% potassium nitrate is worse in desensitizing teeth than using 0.5% potassium nitrate (or no potassium nitrate), it follows that using more than 3% would also be worse than using 0.5% potassium nitrate. Accordingly, to the extent that using 3-50% potassium nitrate is actually *worse* in desensitizing teeth than using 0.5% potassium nitrate, it follows that the vast majority of potassium nitrate concentrations within the scope of claim 1 of the '370 patent provide unexpectedly and unpredictably *worse* tooth desensitization compared to using an amount of potassium nitrate (*e.g.*, 0.5%) within the narrowly tailored ranges recited in the claims of the present application. That further supports the conclusion that the narrowly tailored ranges recited in the claims of the present application are unobvious over the extremely broad range recited in claim 1 of the '370 patent.

Dependent claim 2 of the '370 patent claims potassium nitrate in a range of about 1% to about 7%. Again, because using an amount of potassium nitrate over a majority of the claimed range of claim 2 (*i.e.*, 3-7%) is surprisingly and unexpectedly *worse* in desensitizing teeth than

using an amount of potassium nitrate (*e.g.*, 0.5%) within the narrowly tailored ranges recited in the claims of the present application, it follows that that the claims of the present application are unobvious over claim 2 of the '370 patent.

Finally, dependent claims 14 and 16 of the '370 patent claim potassium nitrate in a range of about 0.1% to about 10%. That means that at least 70% of the potassium nitrate concentrations within the scope of claims 14 and 16 (*i.e.*, 3-10%) are surprisingly and unexpectedly *worse* in desensitizing teeth compared to using an amount of potassium nitrate (*e.g.*, 0.5%) within the narrowly tailored ranges recited in the claims of the present application. From this, it logically follows that the claims of the present application are unobvious over claims 14 and 16 the '370 patent.

Independent claims 13 and 15 of the '370 patent do not specify *any* concentration of potassium nitrate and therefore do not suggest including potassium nitrate within the narrowly tailored ranges recited in the claims of the present application. Moreover, as the specification of the '370 patent suggests that using about 3-10% potassium nitrate is "most preferred" for effecting the desensitizing effect of potassium nitrate (col. 6, lines 57-59), one of skill in the art would not have understood claims 13 and 15 as suggesting the use of an amount of potassium nitrate within the narrowly tailored ranges recited in the claims of the present application. In fact, one of skill in the art would have interpreted the '370 patent and its claims as teaching away from the use of less than 3% potassium nitrate in order to *maximize* the desensitizing effect of the potassium nitrate.

In response to the argument in the Office Action that the comparative study failed to test the desensitizing effect of potassium nitrate when used in combination with a broader range of dental bleaching agent concentrations, Applicants note that it is the amount of potassium nitrate that was discovered by Applicants to be the result-effective variable which controls the desensitization effect of the potassium nitrate, not the amount of dental bleaching agent. It is clear from the comparative study that changing the amount of dental bleaching agent from 10% to 15% (a 50% increase) had virtually no effect on relative tooth and oral sensitivities. In contrast, changing the amount of potassium nitrate from the accepted and usual 3% to 0.5% had an overwhelming effect on reducing tooth and oral sensitivities. Because changing the amount of dental bleaching agent was found to have little, if any, effect on relative tooth and oral sensitivities, there was no need or reason to test the effect of using 0.5% potassium nitrate in combination with a wide range of different bleaching agent concentrations.

Moreover, because the use of three amounts of potassium nitrate (*i.e.*, 0%, 0.5% and 3%) showed the existence of a clear trend relative to reducing relative tooth and oral sensitivities, there was no need or reason to test the effect of using other amounts of potassium nitrate within the narrowly tailored ranges. According to clearly established case law, the detection of a trend in the data will support claiming a broader range of concentrations than the actual data points tested.

In conclusion, Applicants submit that the claims of the present application are unobvious over the claims of the '370 patent because (1) the potassium nitrate ranges recited in claims 1, 2, 14 and 16 of the '370 patent are so broad as to hardly suggest the narrowly tailored ranges recited in the claims of the present application and (2) the comparative study shows that the use of potassium nitrate in an amount (*i.e.*, 0.5%) within the narrowly tailored ranges surprisingly and unexpectedly provided a far greater reduction in relative tooth and oral sensitivities compared to using an amount of potassium nitrate (*i.e.*, 3%) outside the narrowly tailored ranges.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 27th day of January 2010.

Respectfully submitted,



JOHN M. GYNN
Registration No. 36,153
WORKMAN NYDEGGER
Attorney for Applicants
Customer No. 022913

EXHIBIT A

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Ingredients --

Toothpaste

Toothpaste seems to improve every day. We have anti-cavity toothpastes, extra-whitening toothpastes, toothpastes with mouthwash, toothpastes for sensitive teeth, toothpastes with stripes, clear toothpaste, even liver flavored toothpaste for dogs.

A modern toothpaste has many things to do. It must have abrasives to scour off bacterial films. It must have fluorides to harden the teeth against decay. It must have a strong enough flavor to hide the bad tastes of decaying bits of previous meals, and the awful taste of some of the other ingredients, such as detergents and phosphates.

Toothpaste must have thickeners to stay on the toothbrush, and squeeze out of the tube. It must have detergents to remove fatty films, and water softeners to make the detergents work better, and sweeteners, preferably non-nutritive, so bacteria are not encouraged.

Toothpaste ingredients

The most recognized toothpaste ingredient is probably the class of compounds known as fluorides. Stannous fluoride was the first to be used in toothpaste, because it could be used with the abrasive most common at the time, calcium phosphate. The calcium prevents sodium fluoride from being effective.

Later, sodium monofluorophosphate was used, as it also could be used with abrasives common at the time.

When hydrated silica became the abrasive of choice, sodium fluoride could be used, and is the most widely used fluoride in toothpastes at this time.

Hydrated silica is the transparent abrasive used in gel toothpastes, and in the clear parts of striped toothpaste. It has become common to use it in white opaque toothpastes as well, because of its compatibility with sodium fluoride.

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Fluorides work better in combination with surfactants, which help the remineralization process. The most common are the lauryl sulfates, such as sodium lauryl sulfate, or ammonium lauryl sulfate.

Surfactants (detergents) also help clean the teeth, and provide a foam that helps to carry away debris. Moreover, lauryl sulfates have significant anti-bacterial properties, and they can penetrate and dissolve plaque.

Lauryl sulfates can irritate oral membranes, and so a similar detergent, lauryl sarcosinate often replaces some or all of the lauryl sulfate. Allantoin is sometimes added to relieve the irritation caused by detergents, alkalies, and acids.

The sequestering agent tetrasodium pyrophosphate (TSPP) removes calcium and magnesium from the saliva, so they can't deposit on teeth as insoluble deposits called *tartar*, (calcified plaque). In this respect it acts as a water-softening agent. It won't remove tartar that already exists.

TSPP is slightly alkaline, and has a bitter taste, requiring additional flavorings to mask it. Also, additional detergents must be added to keep it in solution. All of these factors can irritate oral membranes and cause sensitivity.

Polymers such as the acrylic PVM/MA copolymer are added to prevent bacteria from breaking down pyrophosphates. Other long polymers used are polyethylene glycol (PEG) in various weights (i.e. PEG-6, PEG-8, PEG-40, etc.), and polypropylene glycol (PPG).

Sodium bicarbonate (baking soda) is added for taste and mouth feel. It combines with acids to release carbon dioxide gas, adding to the foam produced by brushing. It is a mild abrasive. It may reduce the numbers of acid loving bacteria in the mouth, although this effect lasts only as long as the mouth stays alkaline.

Sodium carbonate peroxide is added to "peroxide" toothpastes as a whitener. It breaks down into sodium carbonate (washing soda) and hydrogen peroxide. The hydrogen peroxide bleaches the teeth, and kills germs.

Sweeteners such as sodium saccharin are added for taste. Other flavors are usually strong essential oils in the mint family.

The anti-bacterial agent Triclosan is added to kill plaque-

forming microbes.

Various gums are used to thicken the paste, but also to retain moisture, so the toothpaste does not dry out if the top is not replaced.

In white pastes, titanium dioxide is used to make the paste opaque and white.

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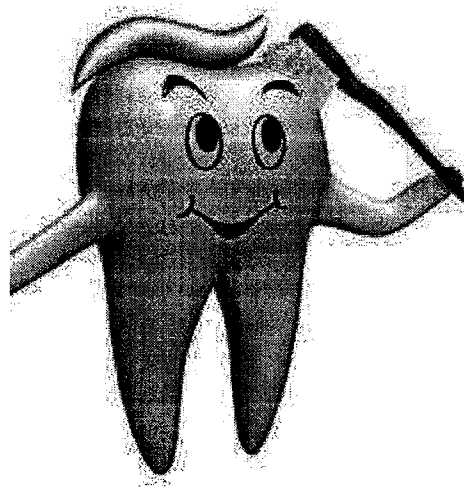
Toothpaste--Is There A Difference?

By Madeline Ellis
Published: Monday, 10 December 2007

Americans brush their teeth almost 200 billion times a year and spend over 1.6 billion dollars on it. There is an entire aisle in your favorite department or grocery store dedicated to toothpastes from many different companies claiming a variety of benefits. But, do they live up to their claims? Is there a difference in them, and how do you choose the one that's right for you?

First, you need to understand how toothpaste works. Your mouth contains one or more of 500 types of microorganisms. These microorganisms feed on leftover food to create acid and particles called volatile sulfur molecules. Some also create sticky plaque from food residue in your mouth. The acid eats into tooth enamel to produce cavities while volatile sulfur molecules give breath its foul odor.

Toothpaste works, with tooth brushing, to clean teeth and fight plaque bacteria.



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- Toothpaste abrasives scrub away plaque, help remove food stains from teeth, and polish tooth surfaces.
- Toothpaste delivers fluoride to the teeth which incorporates itself into tooth enamel weakened by acid.
- Ingredients such as natural Xylitol and artificial triclosan contained in some toothpaste hinder the growth of plaque bacteria.

While each name brand has its own exact formula, most toothpaste contains the same basic ingredients, which are a far cry from those used by the early Egyptians in their dental cream: powdered ashes of oxen hooves, myrrh, burned egg shells, pumice, and water!

Fluoride is perhaps the most important toothpaste ingredient. Fluoride incorporates itself into tooth enamel, making teeth more resistant to acids produced by plaque bacteria, as well as acids found in fruit juices, soda, and certain foods. Fluoride was introduced in the 1950's after tests around the world found that it could dramatically reduce cavities.

Abrasives give toothpaste cleaning power, removing stains and plaque, as well as polishing teeth. Look for toothpaste which is abrasive enough to remove stains and plaque, but not abrasive enough to damage tooth enamel.

Unfortunately, many types of toothpaste are too abrasive and actually strip away tooth enamel which never grows back. Relative Dentin Abrasivity (RDA) was tested in a number of popular toothpaste brands. The least abrasive of those tested was Enamel Saver which scored a 44, Colgate and Crest tested mid-range at 106, and the highest was Close-up at 218. Dentists also recommend that you choose toothpaste that is minimally abrasive.

Detergents create the foaming action which keeps the toothpaste in our mouths. The most commonly used detergent is sodium lauryl sulfate (SLS) which has been linked to the promotion of canker sores in nearly 20% of the population.

Humectants give toothpaste its texture and keep it from drying out.

Thickeners help to create the texture and thickness of toothpaste.

Preservatives prevent the growth of microorganisms in toothpaste, eliminating the need for refrigeration.

Flavoring agents and sweeteners are added to improve the taste of

toothpaste. This is usually necessary due to the bad taste of most detergent additives. Saccharin is a common toothpaste sweetener, and while many people are concerned about its safety, leading researchers say there is 'no danger' from ingesting the tiny quantities you might swallow in toothpaste. Sebastian Ciancio, D.D.S., director of the Center for Dental Studies at the State University of New York at Buffalo says, "It would take about three months of brushing to get the amount you'd put in just one cup of coffee."

Coloring agents provide toothpaste with its pleasing colors.

While ingredients such as **baking soda or peroxide** may give the sensation of a cleaner mouth, most dentists agree that they do very little to clean teeth. Baking soda toothpastes may actually aggravate tooth sensitivity and high blood pressure in those who are susceptible.

What about **whitening toothpastes**? While they remove stains and plaque from your teeth, whitening toothpastes do not increase the whiteness of the underlying tooth. It is also important to note that, due to their harsh abrasives, these toothpastes may, over time, strip tooth enamel, causing teeth to become sensitive and making them appear yellow.

Consumer Reports recently tested 41 toothpastes for their whitening ability and found no connection between the manufacturer's claims and stain-removing ability. Even the seven toothpastes that contain peroxide worked no better overall than other toothpastes at lightening or bleaching out stains.

They did, however, find a toothpaste that stood out as a stain remover: Ultrabrite All in One Advanced Whitening. It was one of the least expensive products tested and was no more abrasive than average.

After wading through a mountain of facts and figures, watching commercials and reading the labels, only one thing rings true when you go about the task of picking toothpaste: generally any toothpaste will work well for you if it contains fluoride.


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Everything You Wanted to Know About Toothpaste

Toothpaste - What's In It?

While the exact formula of each brand of toothpaste is proprietary, most toothpastes contain the same basic ingredients. These include:

Fluoride: Perhaps the most important toothpaste ingredient is fluoride. Fluoride incorporates itself into tooth enamel making your teeth more resistant to acids produced by plaque bacteria, as well as acids found in fruit juices, soda (both regular and diet) and certain foods.

In toothpaste, fluoride is found in the form of sodium monofluorophosphate, stannous fluoride, or sodium fluoride. Prescription toothpastes (for people with dry mouth, Sjogren's syndrome, cancer, etc.) contain a much higher percentage of sodium fluoride than over-the-counter toothpastes.

Abrasives: Abrasives give toothpaste its cleaning power. They remove stains and plaque, as well as polish teeth. Common abrasives include calcium phosphates, alumina, calcium carbonate, and silica. Toothpaste should be abrasive enough to remove plaque and stains, but not abrasive enough to damage tooth enamel.

Stop Brushing w/ Poison

Glacial Blue Tooth Oil-100%
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Unfortunately, some toothpastes are too abrasive, and do damage tooth enamel. This leads to tooth sensitivity. Damaged tooth enamel also causes yellowing as the thinned enamel reveals the yellowish dentin layer below. Over the years, manufacturers have been quietly reducing the abrasiveness of their toothpastes. Consumers should look for these less abrasive toothpastes.

Detergents: Detergents create the foaming action we associate with toothpastes. Foam keeps the toothpaste in our mouths, preventing it from dribbling out as we brush. SLS (sodium lauryl sulfate) is the detergent most commonly used. Unfortunately, SLS and other detergents have been linked to the promotion of canker sores (mouth ulcers) in susceptible individuals. The presence of bad-tasting detergents requires the use of strong flavorings to mask the bad taste.

Humectants: Humectants give toothpaste its texture as well as retain moisture so that your toothpaste does not dry out. Glycerin, sorbitol, and water are common humectants. Xylitol is an uncommon, but superior humectant, which also boosts fluoride's cavity-fighting power.

Thickeners: Thickeners also help to create the texture of toothpaste and determine how 'thick' your toothpaste is. Carrageenan, cellulose gum, and xanthan gum are common thickening agents.

Preservatives: Preservatives prevent the growth of microorganisms in toothpaste. This eliminates the need to refrigerate toothpaste. Common preservatives include sodium benzoate, methyl paraben, and ethyl paraben.

Flavoring Agents: These are added to improve the taste of toothpaste. You may have noticed that toothpastes often have very strong flavoring. This is necessary to cover up the horrid taste of most detergents, especially SLS.

Sweeteners: Sweeteners also improve the taste of toothpaste. Most toothpaste sweeteners are artificial and contribute very little to cavity formation. Saccharin is a common toothpaste sweetener.

Coloring Agents: Some toothpastes would look down right disgusting if it were not for coloring agents. Coloring agents provide toothpaste with pleasing colors. Artificial dyes are used to make red, green, and blue toothpastes. Titanium dioxide is used to make some toothpastes white.

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EXHIBIT D



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/045,489	03/20/98	MCLAUGHLIN	G 09778/002001

REGINALD J. SUYAT
FISH & RICHARDSON
2200 SAND HILL ROAD
SUITE 100
MENLO PARK CA 94025

HM12/0408

EXAMINER

HARRISON, R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/045,489

Applicant(s)

McLaughlin

Examiner

Robert H. Harrison

Group Art Unit

1617

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-32 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 25-32 is/are allowed.
- ☒ Claim(s) 1-24 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- *Certified copies not received: _____
- ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Art Unit 1617

Receipt is hereby acknowledged of applicant's Information Disclosure Statement filed as of March 2, 1998.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7 and 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "about" in claims 2, 4, 6, 17, 19 and 21 is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Ordinarily, the term "about" permits some tolerance but in the instant application as defined by the specification, there is no indication as to the degree of tolerance permitted and thus one having ordinary skill in the art would be forced to resort to undue speculation to determine the precise metes and bounds of the patent protection desired. Further specificity is deemed necessary.

Also in claims 2, 4, 6, 17, 19 and 21, the Examiner observes that each noted claim recites "by weight" but it is not so

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Art Unit 1617

evident on what this phrase is based. Is this "by total weight?" Clarification or further specificity is deemed necessary.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-7 and 9-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Gaffar et al. (U.S. Patent No. 5,648,064).

Gaffar et al. discloses a two component whitening dentifrice composition comprising a bleaching agent encompassing those as claimed and an accelerator or a catalytic accelerator encompassing those as claimed. Please note that "about" in the instant claims directly reads on the amounts disclosed in the reference. Please note that further ingredients such as fluoride, vitamin E and potassium nitrate are disclosed at column 6 in addition to a gel component. The combining would be inherently with the addition of water since the reference discloses such and in any event when it is applied to the teeth, the saliva contains water.

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Art Unit 1617

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9, 11, 16-21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Cornell (U.S. Patent No. 5,032,178).

Cornell discloses aqueous, dental care compositions containing an activator or catalytic accelerator and a bleaching agent used to whiten teeth. Formulations include gels or pastes. Since a paste is disclosed, an abrasive would be inherent in the formulation.

Claims are rejected under 35 U.S.C. 102(b) as being anticipated by Hungerbach et al. (U.S. Patent No. 5,437,858).

Hungerbach et al. discloses what appears to be a silver colloid catalytic activator for hydrogen peroxide oral hygiene agents (compositions) useful in toothpastes. See column 2, lines 19-41.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

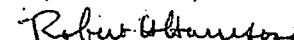
Claims 7, 12-13 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornell and/or Hungerbach et al.

Cornell and Hungerbach et al. have been discussed above. Cornell and Hungerbach et al. do not make explicit mention of the claimed palliative agent and bleaching agents.

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to include the claimed bleaching agents and palliative agent since these bleaching agents are conventional or equivalent to hydrogen peroxide and the claimed palliative agent is a routine additive in toothpastes or oral hygiene compositions.

Claims 25-32 are allowed.

Any inquiry concerning this communication should be directed to Robert H. Harrison at telephone number (703) 308-2422.


Robert H. Harrison
Primary Examiner
Art Unit 1617

RHHarrison:cdc
March 31, 1999

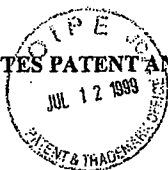
EXHIBIT E

ATTORNEY DOCKET NO. 09778/002001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gerald McLaughlin
Serial No.: 09/045,489
Filed: 3/20/98
Title: ACCELERATED METHOD AND INSTRUMENTATION FOR
WHITENING TEETH

Art Unit: 1617
Examiner: R. Harrison



AMENDMENT UNDER 37 C.F.R. §1.115

Assistant Commissioner for Patents
Washington DC 20231

In response to the Office Action dated April 8, 1999, in connection with the above-identified application, please amend the application as follows:

IN THE CLAIMS:

All of the pending claims have been reiterated for the convenience of the Examiner.

Please cancel claims 8 and 24, without prejudice.

1. (Amended) A composition for whitening of teeth, comprising a therapeutically effective amount of a bleaching compound and a catalytic activator, wherein said catalytic activator is selected from the group consisting of activated charcoal, platinum, a platinum salt, copper, a copper salt, palladium, a palladium salt, silver, and a silver salt and is capable of catalyzing the reaction of said bleaching compound within ten minutes of contacting said catalytic activator with said bleaching compound.

Date of Deposit

I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

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2. (Reiterated) The composition of claim 1, wherein the concentration of said bleaching compound is from about 3 to 40% by weight.
3. (Reiterated) The composition of claim 2, wherein said bleaching compound is selected from the group consisting of carbamide peroxide, carbamyl peroxide, sodium percarbonate, perhydrol urea, and hydrogen peroxide.
4. (Reiterated) The composition of claim 2, wherein the concentration of said bleaching compound is from about 3 to 12% by weight.
5. (Reiterated) The composition of claim 4, wherein said bleaching compound comprises hydrogen peroxide.
6. (Amended) The composition of claim 2, wherein the concentration of said bleaching compound is from about 10 to [about] 40% by weight.
7. (Reiterated) The composition of claim 6, wherein said bleaching compound is selected from the group consisting of carbamide peroxide, carbamyl peroxide, sodium percarbonate, and perhydrol urea.
8. (Canceled) The composition of claim 1, wherein said catalytic activator is selected from the group consisting of activated charcoal, platinum, a platinum salt, copper, a copper salt, palladium, a palladium salt, silver, and a silver salt.
9. (Reiterated) The composition of claim 1, further comprising an abrasive agent.
10. (Reiterated) The composition of claim 1, further comprising an agent for administering fluoride.
11. (Reiterated) The composition of claim 1, further comprising a gel forming agent.

12. (Reiterated) The composition of claim 1, further comprising a palliative ingredient for periodontal tissues.
13. (Reiterated) The composition of claim 12, wherein said palliative agent is selected from the group consisting of aloe, eugenol, and vitamin E.
14. (Reiterated) The composition of claim 1, further comprising an ingredient to decrease tooth sensitivity.
15. (Reiterated) The composition of claim 14, wherein said ingredient to decrease tooth sensitivity is potassium nitrate.

16. (Amended) A method for whitening teeth, comprising combining a bleaching compound with a catalytic agent, wherein the catalytic agent is selected from the group consisting of activated charcoal, platinum, a platinum salt, copper, a copper salt, palladium, a palladium salt, silver, and a silver salt and [catalytic agent] catalyzes the reaction of a significant portion of the bleaching agent within ten minutes while in contact with said teeth.

17. (Reiterated) The method of claim 16, wherein the concentration of said bleaching compound is from about 3 to 40% by weight.
18. (Reiterated) The method of claim 17, wherein said bleaching compound is selected from the group consisting of carbamide peroxide, carbamyl peroxide, sodium percarbonate, perhydrol urea, and hydrogen peroxide.
19. (Reiterated) The method of claim 16, wherein the concentration of said bleaching compound is from about 3 to 12% by weight.

20. (Reiterated) The method of claim 19, wherein said bleaching compound comprises hydrogen peroxide.

21. (Amended) The method of claim 16, wherein the concentration of said bleaching compound is from about 10 to [about] 40% by weight.

22. (Reiterated) The method of claim 21, wherein said bleaching compound is selected from the group consisting of carbamide peroxide, carbamyl peroxide, sodium percarbonate, and perhydrol urea.

23. (Reiterated) The method of claim 16, wherein said combining is by the addition of water.

24. (Canceled) The method of claim 16, wherein said catalytic activator is selected from the group consisting of activated charcoal, platinum, a platinum salt, copper, a copper salt, palladium, a palladium salt, silver, and a silver salt.

25. (Reiterated) A device for whitening teeth, said device comprising a toothbrush comprising a head and a handle, said head having a plurality of bristles, wherein at least one bristle comprises a catalytic activator, and said handle comprising a reservoir for a bleaching compound and a means for dispensing said bleaching compound in close proximity to said bristles.

26. (Reiterated) The device of claim 25, wherein said bleaching compound is selected from the group consisting of carbamide peroxide, carbamyl peroxide, sodium percarbonate, perhydrol urea, and hydrogen peroxide.

27. (Reiterated) The device of claim 25, wherein said catalytic activator is selected from the group consisting of activated charcoal, platinum, a platinum salt, copper, a copper salt, palladium, a palladium salt, silver, and a silver salt.

28. (Reiterated) A device for whitening teeth, said device comprising;
a toothbrush comprising a head and a handle, said head comprising an applicator
and a catalytic activator capable of catalyzing the reaction of a bleaching
compound applied to said head.
29. (Reiterated) The device of claim 28, wherein said head further comprises a retaining
means for holding a bleaching agent in solid form.
30. (Reiterated) The device of claim 28, wherein said applicator is a plurality of bristles.
31. (Reiterated) The device of claim 28, wherein said bleaching compound is selected
from the group consisting of carbamide peroxide, carbamyl peroxide,
sodium percarbonate, perhydrol urea, and hydrogen peroxide.
32. (Reiterated) The device of claim 28, wherein said catalytic activator is selected from
the group consisting of activated charcoal, platinum, a platinum salt,
copper, a copper salt, palladium, a palladium salt, silver, and a silver salt.

Please add the following new claims:

22
33. A composition for whitening of teeth, comprising a therapeutically effective amount of a
bleaching compound and a catalytic activator, wherein said catalytic activator is capable of
catalyzing the reaction of said bleaching compound within ten minutes of contacting said
catalytic activator with said bleaching compound and wherein said bleaching compound is from
about 3 to 40% by weight.

= of claim 2

34. A composition for whitening of teeth, comprising a therapeutically effective amount of a
bleaching compound and a catalytic activator, wherein said catalytic activator is capable of
catalyzing the reaction of said bleaching compound within ten minutes of contacting said

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canceled
catalytic activator with said bleaching compound and wherein the catalytic activator catalyzes the reaction of about 50 to 90% of the bleaching agent.--

REMARKS

These remarks are in response to the Office Action dated April 8, 1999. Claims 8 and 24 have been canceled without prejudice to Applicant's rights to prosecute the canceled subject matter in any continuation, continuation-in-part, divisional or other application. Claims 33 and 34 have been added. Support for claim 33 can be found throughout the specification and in claims 1 and 2 as originally filed. Support for claim 34 can be found in claim 1 and at page 5, line 8 to 10. After amendment, cancellation and addition of the foregoing claims, claims 1-7, 9-23, and 25-34 are pending and at issue. No new matter has been added. Applicant recognizes the Examiner's statement that claims 25-32 are allowable. Applicant respectfully requests reconsideration of the present application and allowance of the claims now pending.

I. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 2-7 and 17-22 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office action alleges that the term "about" in claims 2, 4, 6, 17, 19 and 21 is a relative term which renders the claim indefinite. The Office Action alleges that the specification does not provide a standard for ascertaining the requisite degree. Applicant respectfully traverses.

The term "about" is acceptable if one of ordinary skill in the art can be reasonably apprised of the scope of the invention. The term "about" used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but flexible. *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968). Similarly, in *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch.

Applicant respectfully submits that the term "about" as used in the present claims is clearly set forth in the specification such that one skilled in the art would be apprised of the

scope of the range recited in the claims. For example, Applicant respectfully directs the Examiner to page 4, lines 1-10 of the specification which sets forth a series of ranges regarding the percentage of a bleaching agent of the present invention. For example, the ranges all have a lower limit and an upper limit. Thus, for example one skilled in the art reading the range of "about 3% to 40%" would realize that the lower limit range can be, for example, any percentage from 3% to 20%. Thus, Applicant respectfully submits that the term "about" is not indefinite as alleged in the Office Action, but is set forth in the specification in such a way as to provide a standard for ascertaining the requisite degree such that one skilled in the art would be apprised of the scope of the invention. Accordingly, Applicant respectfully requests withdrawal of the §112, second paragraph rejection.

Claims 2, 4, 6, 17, 19 and 21, also stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. The Office Action alleges that the claim recites "by weight" but it is not so evident on what this phrase is based. Applicant respectfully traverses.

Applicant respectfully directs the Examiner to the table on page 11 of the present specification. The table clearly sets forth how the percentage of the "weight" is determined (*i.e.*, by total weight). Thus, Applicant believes that one skilled in the art would be able to determine the scope of the claims with reference to the present specification. Accordingly, Applicant respectfully requests withdrawal of the present grounds of rejection under 35 U.S.C. §112, second paragraph.

II. REJECTIONS UNDER 35 U.S.C. §102

Claims 1-7 and 9-23 stand rejected under 35 U.S.C. §102 (e) as allegedly anticipated by Gaffar *et al.* (U.S. Patent No. 5, 648,064). The Office Action alleges that Gaffar *et al.* disclose a two component whitening dentifrice composition comprising a bleaching agent encompassing and an accelerator or a catalytic accelerator. Applicant respectfully traverses with respect to the claims as amended.

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990). To anticipate a claim, the reference must teach every element of the claim. *Connell v. Sears Roebuck & Co.*,

220 USPQ 193, 198 (Fed. Cir. 1983); MPEP §2131. Applicant respectfully submits that Gaffar *et al.* does not teach each and every limitation of independent claims 1 and 16.

Gaffar *et al.* teach at col. 2, lines 47-48, that the "activator" is a manganese coordination complex. Gaffar *et al.* does not teach the activators recited in Applicant's claim 1 and 16 (e.g., charcoal, platinum, a platinum salt, copper, a copper salt, palladium, a palladium salt, silver, and a silver salt). Thus, Applicant respectfully submits that Gaffar *et al.* cannot anticipate the present claims. Accordingly, Applicant respectfully requests withdrawal of the §102(e) rejection over Gaffar *et al.*

Additionally, claims 1-6, 9, 11, 16-21 and 23 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Cornell (U.S. Patent No. 5,032,178). Specifically, the Office Action allege that Cornell discloses aqueous, dental care compositions containing an activator or catalytic accelerator and a bleaching agent used to whiten teeth. Applicant respectfully traverses with respect to the amended claims.

Applicant respectfully submits that Cornell does not teach or suggest each and every element recited in Applicant's claims. Cornell teaches a catalytic activator of manganese sulfate monohydrate and ferrous sulfate (see col. 4, lines 25-26). Cornell does not teach or suggest the activators recited in Applicant's claims. In addition, Applicant submits that Cornell adds a silica "gelling" agent and not an abrasive. In fact, Applicant respectfully points out that the compositions of Cornell are not practical for use as an abrasive gel or scrubbing compound. The bleaching agent present in Cornell is highly concentrated (*i.e.*, above 30% by volume hydrogen peroxide; see claim 1) and will elicit burns if splattered onto skin or mucus membranes during "scrubbing" (e.g., brushing of teeth). Rather the compositions of Cornell are designed to be applied to the teeth and not to be scrubbed across or around the teeth. Thus, Applicant submits that the disclosure of Cornell does not teach each and every element of Applicant's claims. Accordingly, Applicant respectfully requests withdrawal of the §102(b) rejection.

The claims additionally stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Hungerbach *et al.* (U.S. Patent No. 5,437,858). Applicant respectfully submits that the

Examiner has not set forth which claims are rejected over Hungerbach *et al.* Accordingly, Applicant respectfully traverses with respect to claims 1-7, 9-23, and 25-34.

The Office Action alleges that Hungerbach *et al.* discloses "what appears to be a silver colloid catalytic activator for hydrogen peroxide oral hygiene agents (composition) useful in toothpastes. See column 2, lines 19-41." (Office Action at page 4). Applicant respectfully submits that Applicant's invention teaches and claims methods and compositions useful in activating (e.g., "destabilizing") a bleaching agent such as hydrogen peroxide. In this regard, Applicant uses activating agents such as, for example, silver or a silver salt. These agents activate (*i.e.*, destabilize) the bleaching agent. In contrast, Hungerbach *et al.* teaches that a silver "colloid" stabilizes (*i.e.*, does not activate) the bleaching agent. Furthermore, Hungerbach *et al.* teach and suggest a desire to stabilize (*i.e.*, not activate) the bleaching agent, thus teaching away from Applicant's invention. Thus, Applicant submits that Hungerbach *et al.* does not teach each and every limitation of Applicant's claimed invention. Accordingly, Applicant respectfully requests withdrawal of the §102(b) rejection.

III. REJECTIONS UNDER 35 U.S.C. §103

Claims 7, 12-13 and 22 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Cornell and/or Hungerbach *et al.* The Office action states that the Cornell and Hungerbach *et al.* references fail to explicitly teach the claimed palliative agent and bleaching agents. However, the Office Action alleges that it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to include the claimed bleaching agents and palliative agent since these bleaching agents are convention or equivalent to hydrogen peroxide and the claimed palliative agent is a routine additive in toothpastes or oral hygiene compositions. Applicant respectfully traverses with respect to the claims as amended.

Applicant respectfully directs the Examiner to the claims which stand rejected. The claims either directly or indirectly depend from claim 1 or 16. Thus, Applicant respectfully reminds the Examiner that if an independent claim is nonobvious under 35 U.S.C. §103 (*i.e.*, claims 1 and 16 of the present application), then any claim depending therefrom is nonobvious (*i.e.*, claims 7, 12-13 and 22). *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988);

MPEP §2143.03. Accordingly, Applicant respectfully requests withdrawal of the §103 rejections

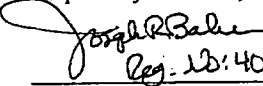
In summary, for the reasons set forth herein, Applicant maintains that the claims clearly and patentably define the invention, respectfully requests that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully requests the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' representative can be reached at (619) 678-5070.

Please charge any additional fees, or make any credits, to Deposit Account No. 06-1050.

Date: 7/7/99

Respectfully submitted,


Reginald J. Suyat
Reg. No. 28,172
Attorney for Applicants

Fish & Richardson P.C.
4225 Executive Square, Suite 1400
La Jolla, CA 92037
Telephone: 619/678-5070
Facsimile: 619/678-5099
94235.LJ1